



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/736,662

12/16/2003

Rosann Marie Kaylor

18,264

5357

23556 7590 03/26/2007  
KIMBERLY-CLARK WORLDWIDE, INC.  
401 NORTH LAKE STREET  
NEENAH, WI 54956

EXAMINER

APANIUS, MICHAEL

ART UNIT

PAPER NUMBER

3736

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|-----------|---------------|
|--|-----------|---------------|

3 MONTHS

03/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/736,662

Applicant(s)

KAYLOR ET AL.

Examiner

Michael Apanius

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3 and 8-41 is/are pending in the application.
- 4a) Of the above claim(s) 3, 8-27 and 35-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/8/2006 has been entered. The cancellation of claims 1, 2 and 4-7 and the addition of new claims 28-41 are acknowledged.

### ***Election/Restrictions***

2. This application contains claims directed to the following patentably distinct species:

- a. Hydrogen-peroxide
- b. Analytes specific to amniotic fluid (Species B is further divided among the following three subspecies)
  - i. Detection with ligand receptor, receptor and cross-linked liposomes (see claim 39)
  - ii. Detecting with analyte sensitive dye encapsulated within a pH sensitive material

Art Unit: 3736

iii. Detecting with pH sensitive dye encapsulated within an analyte sensitive material

c. Cholesterol

The species are independent or distinct because they are directed to different disclosed embodiments of the invention.

2. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 28 is generic.

3. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

5. During a telephone conversation with Vincent Kung on 3/7/2007 a provisional election was made without traverse to prosecute the species of "a", claims 28-34.

Affirmation of this election must be made by applicant in replying to this Office action.

Art Unit: 3736

Claims 35-41 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 30-34 recite further limitations regarding the detection of hydrogen-peroxide. However, it is unclear whether these limitations are actually required by the claim language. For example, claim 28 only requires one of detecting hydrogen-peroxide, analytes and cholesterol. When claim 28 is directed to analytes or cholesterol, the further limitations regarding detection of hydrogen-peroxide are not further limiting since hydrogen-peroxide detection is not required by claim 28.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Kritzman et al. (US 6,921,647). Kritzman discloses a method (Example 1, columns 10-11) of detecting the premature rupture of amniotic membrane comprising: testing a sample of vaginal secretion for pH using a first visual indicator that results in an irreversible change (column 11, lines 5-7) and detecting using a second visual indicator for a relative presence in said vaginal secretion of urea (paragraph bridging columns 10 and 11). In regards to claim 29, vaginal secretion have a pH-level greater than 5 during pregnancy (column 11, lines 5-7).

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3736

13. Claims 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kritzman et al. (US 6,921,647) in view of Macri (US 5,024,936).

14. In regards to claim 34, Kritzman discloses detecting pH of at least 6 (column 11, lines 5-7). Kritzman does not expressly disclose detecting hydrogen peroxide.

15. Macri teaches measuring hydrogen peroxide to determine the presence of phosphatidyl glycerol in amniotic fluid to assess fetal lung maturity (abstract; Example 2 at columns 5 and 6). Hydrogen peroxide is detected with a hydrogen-peroxide mediated enzymatic and non-enzymatic conversion of chromophores (tetramethylbenzidine). The hydrogen peroxide reacts with a peroxidase-treated substrate (column 5, lines 50-53). A relative decrease in hydrogen peroxide will be detected since hydrogen peroxide is measured.

16. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have also detected hydrogen peroxide as taught by Macri in the method of Kritzman in order to obtain additional relevant medical information, such as fetal lung maturity, when amniotic fluid is detected.

### ***Response to Arguments***

17. Applicant's arguments alleging that the new claims overcome the Kritzman reference have been fully considered but they are not persuasive. As noted above, Kritzman meets the limitations of claims 28 and 29.

Art Unit: 3736

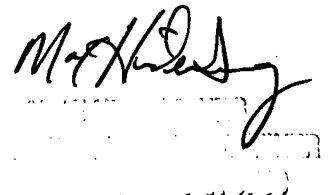
**Conclusion**

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA



Max Hindenburg